

CRITERIA USED FOR EVALUATION OF DATA

Results of only the first 6 weeks of the 12 week study were included because of the high drop-out rate in the second 6 weeks and because of the proposed labeling limit for "short term usage".

Comparison has been limited simply to drug vs. placebo effects because of the small numbers of subjects in the various subgroups according to dosage levels and patient categories.

Only losses of more than 10 lbs. after 6 weeks of treatment have been considered *arbitrarily* as evidence of possible clinically significant drug effect, since non-drug factors may easily account for ± 5 lbs.

"Drop-outs" as tabulated included all patients who failed to have a 6 week weight recorded and one who failed to have a baseline weight.

Investigator qualifications have not been reviewed, except to note that 1 (Grammell) is a Professor of Medicine, 1 (Gattereau) lists an Obesity Clinic in a specialty hospital, and 2 (Stern and Esposito) gave street addresses.